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08/765,324

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER

18N2/0121

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ART UNIT 1817 | PAPER NUMBER 7

DATE MAILED: 01/21/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 10-28-97.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 15-18, 20-23, 25, 27-30, 35-37, 41-47, 45-47 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 15-18, 20-23, 25, 27-30, 35-37, 41, 42 and 45-47 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4, mailed 10/28/97

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

* U.S. GPO: 1996-409-290/40039

DETAILED ACTION

1. The amendment filed 10/28/97 has been entered into the record. Claims 15-18, 20-23, 25, 27-30, 35-37, 41, 42 and 45-47 are pending and under examination. Pursuant to Rule 126, the new claims 43-45 submitted October 28, 1997 have been renumbered 45-47.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not contain a reference to the parent U.S Application Serial No. 08/268,809 since the instant application is a continuation in part.

Election/Restriction

3. The restriction requirement is moot in view of applicants cancellation of the nonelected invention.

Double Patenting

4. Applicant is advised that should claim 18, 20, 21, and 22, be found allowable, claims 35, 36, and will be rejected under 35 U.S.C. 101 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

5. Claims 15-17 and 42, 45-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

As to claims 15-17, the amendment to the claims to remove the immobilized and soluble antibody language is not supported by the international application as originally filed since it never mentions the possibility of adding non-immobilized antibodies in combination with non-immobilized antibodies. Applicant is invited to point to the specification by page and line number for written description support for the amendment to the claims, which provides evidence that applicants conceived this type of assay at the time the invention was made.

As to claims 42, 45-47, upon review of the application, no support for these claims can be found. Applicant is invited to point to the specification by page and line number where written description support for these new filed claims can be explicitly found. These claims were not originally filed with the international application and have no written description basis in the claims of the international application as originally filed.

6. Claim 15-18, 20-23, 25, 27-30, 35-37, 42 and 45-47, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As to claims 15, 16, 17, 42 and 45-47, the claims are missing essential steps which are required to be able to specifically detect the instantly claimed fractions. For example in claim 15,

Apo C-III associated with VLDL or HDL is measured in order to determine the ratio of VLDL to HDL. The specification specifically recites an immobilization of one of the antibodies because in the absence of a separation step or immobilization step, the recited antibodies would not specifically detect the indicated fraction because Apo C-III is present on both VLDL and HDL and thus the particles which bind both APO C-III and pan B must be separated from the lipoprotein mixture and particles which bind both Apo C-III and Apo A-I must be separated from the lipoprotein mixture or the amount of Apo C-III associated with HDL or VLDL can not be determined. The function of these assay requires that the antibodies be immobilized in order to function to separate the indicated fraction. Absent immobilization of the antibodies, the assay will not specifically detect the claimed fractions and thus, will not work. Similar reasoning can be applied to claims 16, 17, 42, and 45-47. In the absence of further guidance from applicants and that the specification requires that particular antibodies must be immobilized for the assay to operate, it would require undue experimentation on the part of the skilled artisan to make and use the assay as instantly claimed and the claims should be so limited.

As to claims 15-17, 21, 22, 28, 29, 30, 36, and 37, the claims require specific monoclonal antibodies or antibodies with similar characteristics, in order to determine that the prior art antibodies are "similar to" the recited antibodies, the specific monoclonal antibodies would be required to be publicly accessible. The specification lacks complete deposit information for the deposit of cell lines for the recited monoclonal and recombinant antibodies. Because it is not clear that cell lines possessing the properties of producing monoclonal or recombinant antibody which specifically binds the apolipoproteins are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of or comparison to these antibodies, a suitable deposit for patent purposes is required.

Accordingly, filing of evidence of the reproducible production of the cell lines claimed is required. Without a publicly available deposit of the above cell lines, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event. Note that the best mode is not satisfied by a written disclosure unless the exact embodiment is reasonably reproducible from that disclosure. If reproducibility of the cell line is not established, failure to deposit the cell line would result in concealment of the best mode contemplated by applicant for carrying out the invention. In re Sherwood, 615.2d 809,204 USPQ 537 (CCPA 1980).

Applicant's referral to the deposit of the hybridoma cell lines in the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR §1.801-1.809 have been met.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;
(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;
(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and
(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;
2) The name and address of the depositor;
3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if the test is not done by the depository; and
7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the hybridoma cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

As to claims 18, 19, 20, 23, 25, 27, 28, 29, 30, 35, and 32, the specification only teaches and provides a description of the production of a **single** monoclonal antibody HB_3cB_3 and recombinant antibody $RcB_3M_1D_4$, that specifically binds "..a stable, conformation independent epitope which is uninfluenced by the lipid content" which have affinity constants greater than 10^9. The specification teaches that the monoclonal and recombinant antibody displaying these properties binds to an epitope near the T2 carboxy terminal region of B-100 and does not recognize B-48 and that this antibody specifically binds ApoB-100 on LDL but not VLDL or chylomicrons. The specification does not teach the ApoB protein sequence of this epitope. Absent an adequate written description of the epitope which the monoclonal or recombinant antibody binds, and lacks an adequate written description of the production of other monoclonal antibodies with these properties such that it is not apparent from the teaching of the specification that monoclonal antibodies with the instantly claimed properties can be predictably reproduced. Absent further guidance from applicants as to the sequence of the specific epitope bound by HB_3cB_3 and in the absence of an adequate written description of other monoclonal antibodies

with identical binding properties, it appears that undue experimentation would be required to make other monoclonal antibodies with the specific binding properties and thus the claim should be so limited.

As to claims 18, 20, 23, 25, 27, 30, 35 and 42, the specification fails to provide an enabling and adequate written description of other monoclonal antibodies which specifically bind other apolipoproteins or lipoproteins with the instantly claimed characteristics. The written description of the claimed properties in relation to lipoprotein and apolipoprotein monoclonal antibodies is limited to the section entitled "Antibodies to Apo B-100". Since, the specification does not teach that the ApoB-100 epitope on LDL is specifically conserved in the other apolipoproteins and since the apolipoproteins are well known in the art to be distinct proteins by sequence, function and antigenicity, it is not apparent that teachings for production of antibodies and methods for ApoB-100 on LDL as disclosed in the specification, predictably and reproducibly apply to all the other apolipoproteins (i.e. ApoA-I, ApoA-II, ApoB-48, ApoC-III, and ApoE) and lipoproteins (i.e. chylomicrons, HDL and VLDL). Absent further guidance from applicants, and in view of the lack of teachings for the other lipoproteins or apolipoproteins and working examples, it appears that undue experimentation on the part of the skilled artisan would be required to practice the invention for other apolipoproteins and lipoproteins.

As to claims, 15-17, 18, 23, 25, 27, 28, 29, 30, 35, 42, and 45-47, the term "antibody" or "antibody fragment" encompasses both polyclonal, monoclonal antibodies and recombinant antibodies. The specification is not enabled for polyclonal antibodies. The specification fails to teach how to predictably and reproducibly make antibodies to lipoproteins, apolipoproteins or lipid associated lipoproteins with the instantly claimed binding properties. The art specifically

teaches that the production of polyclonal antiserum is variable and not readily reproducible.

Campbell et al (page 3, column 2) teach that

> "Polyclonal antiserum consists of a wide variety of antibody molecules of different specificity and affinity (Fig. 1.1). Each time an animal is bled, it yields a different 'cocktail' of such antibodies as its immune response to the injected and environmental antigen alters and B cell clones emerge and recede. The same animal can yield a highly specific antiserum directed against the chosen antigen in one bleed and a poor antiserum in another . The animal also has a limited lifespan and prior to the days of Mab technology, the death of a single rabbit could cause major problems is a diagnostic laboratory.
>
> There is an additional inter-animal variability among animals which cannot readily be inbred in the same way as small rodents can be inbred to yield pure strains with matching histocompatibility antigens (Section 3.4). While large 'outbred' animals such a s rabbits, sheep and goats, can yield a large quantity of specific antibody, their response to antigen is variable and it was often necessary to immunise up to 30 animals to obtain a high-affinity antiserum."

It would therefore require undue experimentation on the part of the skilled artisan to make polyclonal antibodies with the instantly claimed binding specificity absent further guidance from applicants. Moreover, applicants recitation of affinity constants can not be scientifically determined for polyclonal antibodies and therefore applicants disclosure is limited to monoclonal antibody HB_3cB_3 and recombinant antibody $RcB_3M_1D_4$ and fragments thereof which bind, provided that the deposit requirements set forth above are perfected.

For the foregoing reasons, in the absence of further guidance from applicants it would require undue experimentation on the part of the skilled artisan to make and use the invention as instantly claimed.

7. Claims 15-17, 28-30, 41, 42, and 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to method claims 15, 16, 17, 42, 45-47, the claims are so confusing as to when each antibody is being added wether the antibodies are added together or separate or if the sample is

separated into two aliquot or processed in the same sample. For example, the claims are so unclear as to how to determine the amount of ApoC-III present in VLDL or HDL without a separation step because the antibodies added would not apparently separate the indicated fraction. Clarification is respectfully requested.

As to claims 15, 16, 17, 28, 29, 30, require a binding affinity "similar to" or with a specific monoclonal antibody. The phrase "similar to" or "with" renders the claims indefinite because there is no art defined limitation of the range which encompasses "similar to" and thus the metes and bounds of the antibodies used in the claims can not be determined.

As to claims 28, 29 and 30, the claims are confusing because the terms lack antecedent basis in the independent claim 18. Thus, it is unclear as to how the claim further limits the independent claim since it fails to recite "the" or "said" antibody or further comprising. Thus, it is unclear as to how the antibodies of the dependent claim relate to the independent claim 18.

As to claim 41, the claim is rendered indefinite because it depends from a canceled claim.

Claim Rejections - 35 USC § 102 or 103

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 17 is rejected under 35 U.S.C. § 102(b) as being anticipated by Koren et al (Atherosclerosis, 95:157-170, 1992; herein after referred to as Koren A) or Koren et al (Clin Chem, 33(1):38-43, 1987, herein after referred to as Koren B).

It is noted that Lp-A-I and A-II are equivalent to the Apo A-I and Apo A-II of the instant claim.

Koren A teaches a method for determining the concentration of Lp-A-I and Lp-A-I:A-II which meets all the limitation of the steps of the instant claim (page 161, column 1, see "enzyme linked immunosorbent assay of lipoprotein particles containing apo A-I) wherein the concentration of Lp-A-I and Lp-A-I:A-II are specifically measured and compared.

Koren B et al also teaches the same method for determining the concentration of Lp-A-I and Lp-A-I:A-II which meets all the limitation of the steps of the instant claim wherein the concentration of Lp-A-I and Lp-A-I:A-II are specifically measured and compared.

11. Claims 18, 20, 23, 25, 27, and 30 are rejected under 35 U.S.C. § 102(a) as being anticipated by Kundu et al (WO 93/18067, 16, September 1993).

Kundu et al teach that monoclonal antibodies which bind the T2 fragment of ApoB have less cross-reactivity to VLDL and IDL (page 33, lines 30-34).

> "Thus, MABs, which are specific for the apo B T2 fragment or sub-fragments thereof, will bind to the apo B T2 fragment and LDL, but will have low (less than 20%) cross-reactivity with VLDL, IDL and Lp(a). Such MABs would be useful in selectively binding LDL in the presence of other lipoproteins."

Kundu et al teach the monoclonal antibody 4B5.6 which has minimal cross-reactivity with VLDL and IDL and which binds the T2 region. Kundu et al also teach other monoclonal antibodies which specifically bind this region. Kundu et al teach immobilization of the antibody onto a solid phase (page 59 and 66, see examples 4 and 12 respectively). Kundu et al teach a protocol for an indirect LDL-cholesterol assay with dry antibody gels using a plasma sample (page 66, see example 13). Kundu et al also teach monoclonal antibodies to lipoprotein (a) (i.e. LP(A)) which did not cross-react with LDL, VLDL IDL and HDL, immobilization of the monoclonal antibody onto a solid phase and detection of lipid-associated cholesterol from plasma using the immobilized anti-lipoprotein (a) monoclonal antibody (pages 68-72). Kundu et al teach the advantage of the antibody is that it separates LDL from plasma without an ultracentrifugation step with minimal cross-reactivity with other lipoproteins. Although the reference discloses minimal cross-reactivity with VLDL, since it binds to the same region (T2) of ApoB it would reasonably be expected to have the same properties as the ApoB monoclonal antibody disclosed by the specification. Kundu et al teach lipoprotein and apoliproprotein standards and calibrators for use in the assay with the monoclonal antibody and thus the disclosure anticipates the instant compositions and absent convincing evidence to the contrary, it is apparent that the monoclonal antibody 4B5.6

inherently possesses the instantly claimed property "...specifically binds to a stable, conformation independent epitope which is uninfluenced by the lipid content.." and the disclosure anticipates the instant compositions for use of measuring specific lipoproteins and their associated cholesterol.

12. Claims 18, 20, 23, 25, 27, and 30 are rejected under 35 U.S.C. § 102(b) as being anticipated by LaBelle et al (Clinica Chimica Acta, 191:153-160, 1990).

LaBelle et al teach an enzyme linked immunosorbent assay (ELISA) for the detection of ApoB containing LDL in whole plasma using a monoclonal antibody specific for LDL and ApoB which specifically binds the T2 fragment (see pages 155-156, and Figure 1) as does the monoclonal antibody disclosed in the specification. Although the reference is silent on the ability of the antibody to bind to VLDL, since it binds to the same region (T2) of ApoB it would reasonably be expected to have the same properties as the ApoB monoclonal antibody disclosed by the specification. Absent convincing evidence to the contrary, it is apparent that this antibody inherently possesses the instantly claimed property "...specifically binds to a stable, conformation independent epitope which is uninfluenced by the lipid content..".

13. Claims 18, 20, 23, 25, 27, 28, 29, 30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kundu et al (WO 93/18067, 16, September 1993) or LaBelle et al (Clinica Chimica Acta, 191:153-160, 1990) in view of Koren et al (Atherosclerosis, 95:157-170, 1992).

Kundu et al (WO 93/18067, 16, September 1993) or LaBelle et al (Clinica Chimica Acta, 191:153-160, 1990) are set forth supra. Kundu et al or LaBelle et al differ by not including the other recited apolipoprotein specific antibodies in a kit or composition. In addition, both Kundu et

al and LaBelle et al teach that measurement of lipoproteins and cholesterol associated with lipoproteins is medically important.

Koren et al teach monoclonal antibodies which bind Apo-AI, Apo-AII, Apo-CIII, Apo-B, pan Apo-B and specifically identify CDb5, AbA3, EfD3 and standards to measure lipoprotein particles (see pages 161-165, see sections entitled *Analytical procedures, Enzyme-linked immunosorbent assay of lipoprotein particles containing apo A-I, Principle of the method, Monoclonal "pan" apo B antibody and biotinylated polyclonal antibody to apo B, Primary standards, Secondary standards and controls and Details of the method*). Koren et alt each that there are reports that indicate the potential clinical significance of certain lipoprotein subspecies are either atherogenic or antiatherogenic (see page 157, summary).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to assemble the lipoprotein and apolipoprotein reagents of Kundu et al and Koren et al or LaBelle et al and Koren et al for perform the methods therein in a single composition or kit format because Koren et al , Kundu et al, and LaBelle et al all teach that apolipoproteins, lipoproteins and associated cholesterol are medically important, and the assembly of reagents in a kit format is routine and conventional in the art.

Status of Claims

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 6:30 AM to 3:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application should be directed may be submitted to Group 1800 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The FAX number for Art Unit 1817 is (703) 308-4242.

Patricia A. Duffy, Ph.D.
January 20, 1998

Patricia A. Duffy

Patricia A. Duffy, Ph.D.
Patent Examiner
Group 1800